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D Peter Hochberg Company
The Baker Building 6th Floor
1940 East 6th Street
Cleveland, OH 44114-2294

EXAMINER

PALENIK, JEFFREY T

ART UNIT	PAPER NUMBER
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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,849	Applicant(s) WESSLING, WERNER	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 17-19, 21, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 17-19, 21, 34 and 35 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of Applicants' Amendments and Remarks filed 9 June 2008.

The Examiner acknowledges the following:

Claims 1, 3, 5, 6, 18 and 21 have been amended. Support for the amendments, while not expressly provided, was found either within Applicant's disclosure and/or the previously filed claims.

New claims 34 and 35 have been added. Support for the newly added claims is stated as being found in ¶¶ [0009] and [0010].

No claims have been cancelled.

Thus, claims 1-8, 17-19, 21, 34 and 35 now represent all claims currently under consideration.

PRIORITY

Applicants continuity of priority has been verified via the documents previously submitted. The Examiner thanks Applicants for pointing out the incorrectly applied time requirement. However, Applicant is still denied priority to DE 102 26 494.5, filed 14 June 2002, since no distinguishable English translation of the Foreign Application has been submitted. Per MPEP §1893.01(d), an English translation of the international application is required when entering the national stage in the U.S. Applicant's response indicates that such a translation was submitted. However, after examining each document submitted by Applicant on 9 June 2008, the Examiner respectfully submits that an English translation cannot be discerned. Otherwise stated, there were no submissions by Applicant indicating either a certified translation of the

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foreign application or any documents (i.e. Specification, claims, etc.) demonstrating clear and unswerving continuity back to the foreign application. Until such time as this is provided, Applicant's effective U.S. filing date will remain 8 May 2003.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendments to both the Abstract of the Invention render the objections to the Specification moot. Thus, said objections have been **withdrawn**.

Rejection under 35 USC 112

Applicant's amendment to claim 1 renders the rejection to the claim, under 35 USC 112, second paragraph, moot. Thus, said rejection has been **withdrawn**. Furthermore, the Examiner would greatly appreciate a certified translation of the Rompp Lexikon Chemie reference to Hashish.

Applicant's amendment to claim 3 renders the rejection to the claim, under 35 USC 112, second paragraph, moot. Thus, said rejection has been **withdrawn**.

Applicant's amendments to claims 1 and 6 render the antecedent basis rejection to claim 6, under 35 USC 112, second paragraph, moot. Thus, said rejection has been **withdrawn**.

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Applicant's amendments to claims 1 and 6 render the antecedent basis rejection to claim 6, under 35 USC 112, second paragraph, moot. Thus, said rejections have been **withdrawn**.

Applicant's amendments to claims 1, 6 and 21 render the rejection to claims 6 and 21, under 35 USC 112, second paragraph, moot. Claim 1 was amended such that the thickness expressly refers to the administration form. Thus, said rejection has been **withdrawn**.

Rejection under 35 USC 102(b)

Applicant's supported amendments to claim 1, particularly wherein the administration form comprises at least one further cannabinoid compound, renders moot, the rejection to claims 1-3, 5-8, 17, 19 and 21 under 35 USC 102(b) as being anticipated by Yates (USPN 6,319,510). Thus, said rejection has been **withdrawn**.

Rejection under 35 USC 102(b)

Applicant's supported amendments to claim 1, again, namely wherein the administration form comprises at least one further cannabinoid compound, renders moot, the rejection to claims 1-8, 17-19 and 21 under 35 USC 102(b) as being unpatentable over Yates. Thus, said rejection has been **withdrawn**.

NEW REJECTIONS

In light of Applicants' amendments, most notably to claim 1, as well as the addition of new claims 34 and 35, the following rejections have been newly added:

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Claim Objections

Claim 1 is objected to because of the following informalities: the amendment made to claim 1 includes the following recitation: “{consisting}”. It is unclear to the Examiner how to interpret this recitation, particularly since it is unclear whether or not the term is being removed. Herein, for the purposes of examination on the merits, the Examiner will broadly and reasonably interpret the above recitation as “comprising”.

Regardless as to whether or not this interpretation is in line with Applicant’s intended invention, appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The newly added claim 34 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The instant claim 34 is drawn to the cannabis extract mucoadhesive film administration form of claim 1, wherein the cannabis extract is further defined as “a cannabis oil”. Applicants’ response, dated 9 June 2008, states the addition of claim 34, reciting paragraphs [000009] and [000010] as support. After carefully examining the instant disclosure, particularly ¶¶[000009] and [000010], the Examiner respectfully submits that support for this

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amendment is lacking and the addition of said limitation constitutes **new matter**. The Examiner further searched the specification and respectfully submits that while there is support for the incorporation of “cannabis oils” into the present administration form, there is nothing disclosed that would suggest that cannabis extracts and oils are synonymous or even that cannabis oil is an embodied species of cannabis extract (see also ¶¶[000014] and [000026]). Referring to Applicants’ ¶[000009], there is nothing disclosed to indicate that cannabis extracts are further limited to cannabis oils or even that the oils are derived from or are a form of extract. As such, the disclosure of the instant specification is not sufficient to support the generic concept of “wherein the cannabis extract is a cannabis oil” and requires further clarification. As construed in the prior art, the Examiner is interpreting the term “cannabis oil” as being a product which is independent of “cannabis extracts” (See US Pre-Grant Publication No. 2003/0017216; ¶¶[0008] and [0009]). Broadly and reasonably considered, the new limitation is interpreted as a limitation which does not further limit the composition of amended claim 1. Thus for the purposes of examination on the merits the newly added claim 34 will be interpreted as reciting the same subject matter as the instantly amended claim 1.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 17-19, 21, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (US Pre-Grant Publication No. 2002/0136752).

The instant amended claims are drawn to a film-shaped mucoadhesive composition containing a cannabis extract comprising tetra-hydrocannabinol (THC) and at least one further cannabinoid, said film having a thickness of 0.5 mm or less (claim 1). The polymer administration form is recited as comprising a polymer matrix and representing a percent by weight of the composition (claims 2, 3 and 17). The administration form is recited as comprising a percentage of cannabis extract (claims 4 and 18). The administration form is recited as further comprising additional flavoring and odorous compounds (claims 5 and 19). The thickness of the overall composition is further limited (claims 6 and 21). The administration form is recited as further comprising at least one inactive ingredient (claim 7) and as having multiple layers wherein at least one layer contains an active agent (claim 8). New claim 34, as discussed above, does not further limit claim 1 since, cannabis oils, absent a clearer definition, are interpreted in the same scope as cannabis extracts. Claim 35 recites species limitations to cannabinoids.

Whittle et al. teach a film-shaped, pharmaceutical formulation for administration to a mucosal surface, wherein the formulation comprises at least one lipophilic medicament and a

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matrix which comprises at least one emulsifying agent and a sweetening or flavoring agent (claim 1 and Examples 9). Example 9 expressly teaches a melted mass (i.e. matrix) formulation which serves as a reservoir for two cannabis active ingredients: tetrahydrocannabinol (THC) and cannabidiol (CBD). The formulation expressly teaches the presence of a cannabis extract (e.g. THC) and a cannabinoid compound present, each in the amounts of 5 parts per 90 parts (e.g. about 5.5% by weight). Absent any evidence to the contrary, the units “parts” is interpreted by the Examiner as teaching “percent by weight”. This expressly teaches the instantly claimed limitations of claims 1, 2, 4, 18, 34 and 35. The composition of Example 9 further teaches the instantly claimed a water-soluble polymer limitation of claims 3 and 17 whereby it contains gum Acacia (e.g. a water-soluble natural gum) in the amount of 20 parts per parts (e.g. about 22% by weight). The Example also teaches the instantly claimed odorous substances limitation of claims 5, 7 and 19 whereby the taught composition contains vanillin. The limitations of claim 7 are also expressly taught by both claim 1 and Example 9, which respectively teach the inclusion of an emulsifying agent in the form of glyceryl monoleate. Lastly, Example 9 and Figures 1-4 teach that the composition must not only be able to fit comfortably inside oral cavity, but also conform to a thickness requirement. Example 9 expressly teaches a preferred thickness of 2.5 mm, achieved by rolling out the hot-melted mass into a sheet. Example 11 expressly teaches the limitations of the instant claims 1, 2, 4, 8 18, 34 and 35, whereby the mucoadhesive composition comprises both a cannabis extract and a cannabinoid, again THC and CBD, and within the claimed percentages. The limitations of claim 8 are expressly taught in Example 11, which teaches a two-layered composition the first layer of which comprises THC in the amount of 15 parts per about 133 parts (e.g. about 7.5% by weight) and the second layer of which comprises

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CBD in the amount of 20 parts per about 165 parts (e.g. about 12.1% by weight). The overall composition thus comprises 15 parts per about 298 parts of THC (e.g. about 2% by weight). The overall composition further comprises 15 parts Acacia gum and 100 parts glycolgelatin per 298 parts (e.g. about 38.6% by weight) as well as glyceryl monoleate as the emulsifying agent.

Example 10, which teaches no specific formulations, serves to further elaborate on the final forms which are applicable to the different Examples, citing specifically that the melted molds may be molded or cast into films.

Though Whittle expressly teaches nearly every aspect of the instantly invention, the teachings do not expressly teach the overall administration form as conforming to the instantly claimed thickness limitations.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the instantly claimed single- or multi-layered, cannabis extract/cannabinoid mucoadhesive administration form, as taught and suggested by Whittle, modify the thickness of the cast film form, and produce the instantly claimed invention.

One of ordinary skill in the art would have been highly motivated to do this because Whittle expressly teaches each of the aforementioned aspects of the instantly claimed invention with the exception of conforming said article to the claimed dimensions. Furthermore, as discussed above, in view of Figures 1-4 and Examples 9-10 of the invention practiced by Whittle, it would have been *prima facie* obvious to a person of ordinary skill in the art to optimize the thickness parameter of the administration forms (see MPEP §2144.04 (IV)(B.)) for any number of reasons related to the efficacy or aesthetic aspects of the invention (i.e. to be able

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to accommodate the variety different oral or buccal locations to which the form will be applied). Thus, absent some demonstration of unexpected results or criticality from the claimed parameters, optimization of any of the thickness parameter would have been obvious at the time of Applicant's invention.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this

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final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966.

The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615